

## **REMARKS**

### **Regarding the Amendments**

Upon entry of the amendments, claims 26 and 30 through 58 will be pending. Claims 34 and 36-44 have been withdrawn from further consideration by the Examiner as being drawn to a non-elected invention or species. Claims 26, 30 and 47-50, currently on file, have been amended to more clearly define the scope of protection being sought. New claims 54 to 58 have been added to claim additional embodiments of the invention. Support for the amendments and new claims can be found throughout the specification as filed. Applicant asserts that no new matter has been added by way of these amendments.

### **Abstract Objections**

The Examiner has objected to the Abstract and has suggested that Applicant delete "[t]he present invention provides for" on lines 1, 5, 6, and 8 of the Abstract to be more clear and concise.

Applicant is submitting herewith an amended Abstract in which the phrase "[t]he present invention provides for" (and variations thereof) on lines 1, 5-6, and 8 has been deleted in accordance with the Examiner's suggestion. Applicant submits that the amended Abstract is both clear and concise and, therefore, respectfully requests that the Examiner withdraw this objection.

### **Claim Rejections - 35 USC § 112, 1st**

The Examiner has rejected claims 48, 49 and 53, currently on file, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleged that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner stated that skin ageing or dermatological conditions cannot be prevented

and alleged that there is no evidence that one would never get skin ageing by consuming the claimed plant extracts of *Chenopodium quinoa*. The Examiner stated that unless Applicant can show on the record that skin ageing would be completely prevented in every instance, Applicant is requested to cancel the word "preventing."

The Examiner further rejected claims 48, 49 and 53 under 35 U.S.C. 112, first paragraph. The Examiner alleged that the specification, while being enabling for treating skin ageing, does not reasonably provide enablement for preventing skin ageing.

Applicant respectfully traverses the Examiner's rejection for the following reasons. As stated in the MPEP at § 2111, pending claims should be "given their broadest reasonable interpretation consistent with the specification," however, "[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." (Emphasis added). In this regard, the MPEP references *In re Cortright*, 165 F3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999), in which "[t]he Board's construction of the claim limitation "restore hair growth" as requiring the hair to be returned to its original state was held to be an incorrect interpretation. The court held that, consistent with applicant's disclosure and the disclosure of three patents from analogous arts using the same phrase to require only some increase of hair growth, one of ordinary skill in the art would construe "restore hair growth" to mean "that the claimed method increases the amount of hair grown on the scalp, but does not necessarily produce a full head of hair." Similarly, in the present case, Applicant asserts that a worker skilled in the art, having reference to the instant application and the state of the art, would appreciate that the term "preventing" in the context of skin ageing is intended to require only some degree of prevention, such as delaying the onset of skin ageing, retarding the appearance of one or more of the effects of skin ageing, slowing the progression of one or more effects of skin ageing, and the like, rather than complete prevention, as suggested by the Examiner.

In this regard, Applicant also respectfully directs the Examiner to the state of the Patent Registry with respect to compounds or compositions for use in preventing skin ageing. The Registry contains numerous examples of issued patents claiming methods or

compositions for preventing skin ageing or dermatological changes in the skin. For instance:

1. U.S. Patent No. 7,341,712, issued on March 11, 2008.

Claim 34 of this patent recites: A method of treating or ***preventing*** cosmetic or ***dermatological changes in skin***, wherein the method comprises applying to the skin a cosmetic or dermatological preparation which comprises (a) at least one hydroxybenzophenone and (b) at least one benzoxazole derivative. (Emphasis added).

2. U.S. Patent No. 7,326,420, issued February 5, 2008.

Claim 17 of this patent recites: A method of ***preventing*** or reducing ***skin aging*** comprising applying to the skin a combination of a peroxide and a tertiary amine, the tertiary amine increasing radicals formed by the peroxide on the skin to thereby increase the efficacy of the peroxide in preventing or reducing skin aging. (Emphasis added).

3. U.S. Patent No. 7,282,522, issued October 16, 2007.

Claim 5 of this patent recites: A skin-care external composition for ***preventing*** ***skin aging***, containing the hydroxamic acid derivative according to claim 1 as an active ingredient. (Emphasis added).

4. U.S. Patent No. 7,105,570, issued September 12, 2006.

Claim 1 of this patent, for example, recites: A method for ***preventing*** or treating a ***disorder*** caused or promoted by an oxidative stress mediated by a transcriptional regulatory factor NF- $\kappa$ B or AP-1, which method comprises applying onto the skin of a subject in need thereof a cosmetic composition or a dermatologic preparation for external use comprising, as an effective ingredient, at least one compound represented by formula (III) or a salt thereof: .....***wherein said disorder is selected from the group consisting of skin aging***, wrinkles, skin inflammation, sunburn, xeroderma pigmentosum or solar urticaria, photoallergy, optical immunosuppression, rough skin caused by injury,

rough skin caused by chaps, rough skin caused by cleft, atopic dermatitis, contact dermatitis, and psoriasis vulgaris. (Emphasis added).

5. U.S. Patent No. 6,924,400, issued August 2, 2005.

Claim 15 of this patent recites: A regime or regimen for **preventing** and/or treating photo-induced or chronological **aging of the skin**, comprising administering to an individual subject in need of such treatment, for such period of time as required to elicit a desired therapeutic effect, a thus-effective amount of the cosmetic composition as defined by claim 13. (Emphasis added).

Accordingly, Applicant asserts that the subject matter of claims 48, 49 and 53, currently on file, is fully described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

With respect to the Examiner's allegation that the specification, while being enabling for treating skin ageing, does not reasonably provide enablement for preventing skin ageing, Applicant respectfully disagrees. As noted above, a worker skilled in the art, having reference to the instant application and the state of the art, would appreciate that the term "preventing" in the context of skin ageing is intended to require only some degree of prevention, such as delaying the onset of skin ageing, retarding the appearance of one or more of the effects of skin ageing, slowing the progression of one or more effects of skin ageing, and the like. The present specification provides extensive teaching regarding the preparation of the plant extracts (see, for example, page 18, line 20 to page 22, line 29), testing the plant extracts for their ability to affect cellular activities in skin that are associated with skin ageing (see, for example, page 16, line 7 to page 31, line 20), and how to formulate the plant extracts for administration (see, for example, page 36, line 22 to page 46, line 5). Furthermore, the specification provides numerous Examples demonstrating the activity of various plant extracts, not only in inhibiting extracellular proteases associated with skin ageing effects (see, for example, Example II), but also in inhibiting cellular activities that lead to skin ageing (see, for example,

Examples VI, XII and XIV), as well as in promoting collagen formation (see Example XI). Accordingly, the Applicant asserts that the instant specification is fully enabling not only for treating skin ageing, as noted by the Examiner, but also for preventing skin ageing.

For the reasons set forth above, Applicant asserts that claims 48, 49 and 53, submitted herewith, comply with 35 U.S.C. 112, first paragraph, and, therefore, respectfully requests that these rejections be withdrawn.

**Claim Rejections - 35 USC § 112, 2<sup>nd</sup>**

The Examiner has rejected claims 30, 47 and 51, currently on file, under 35 U.S.C. 112, second paragraph. The Examiner alleged that these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner stated, regarding claim 30, Applicant is required to spell out the abbreviation "UV" in line 3. The Examiner further stated that claim 47 recites the limitation "the skin in a subject" in lines 1-2 and alleged that there is insufficient antecedent basis for this limitation in the claims. Regarding claim 51, the Examiner stated that this claim is not specifically recited for containing indefinite matter, but because this claim is dependent on claim 47 and does not remedy the alleged indefiniteness in claim 47, this claim is also rejected under this statute.

Without conceding to the correctness of the Examiner's position, but solely in order to expedite prosecution of the application, Applicant has amended claim 30 and claim 47 (on which claim 51 depends). Specifically, Applicant has replaced the abbreviation "UV" in claim 30 with the term "ultraviolet," and has deleted the word "the" from the phrase "'the skin in a subject" in claim 47. Applicant asserts that claims 30, 47 and 51 submitted herewith comply with 35 U.S.C. 112, second paragraph, and, therefore, respectfully requests that this rejection be withdrawn.

### **Claim Rejections - 35 USC § 102/103**

The Examiner has rejected claims 26, 30-33, 35 and 45-53 under 35 U.S.C. § 102 (b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 (a) as obvious over JP 2000336024A (N). The Examiner stated that JP 2000336024A teaches cosmetic (dermatological) compositions containing one or more humectant plant extracts of *Chenopodium quinoa* etc. for dry skin. The Examiner alleged that the composition disclosed by JP 2000336024A is not precluded for carrying out the intended function of the claims because the referenced composition comprises one and the same ingredient disclosed by Applicant as having the claim-designated functions. The Examiner alleged that, consequently, the claimed method and composition appears to be anticipated by the reference, although the reference does not explicitly teach that the plant extracts of *Chenopodium quinoa* inhibit the activity of matrix metalloprotease-9 (MMP-9) or increase collagen production.

The Examiner further alleged that, in the alternative, even if the claimed invention is not identical to the referenced composition/method with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced method is likely to inherently possess the same characteristics of the claimed method composition particularly in view of the similar characteristics which they have been shown to share. Specifically, the Examiner alleged that since the cited reference teaches the claimed plant extract (*Chenopodium quinoa*) with the claimed properties, namely, effective for skin treatments that prevent, alleviate or improve such conditions as dryness, rough skin, cracks, chaps, dandruff, pruritis and inflammatory diseases, it is deemed that inhibiting the activity of matrix metalloprotease-9 (MMP-9) or increasing collagen production is the intrinsic mechanism/pathway of the claimed plant extract and that the claimed method would have been obvious to those of skill in the art with the meaning of 35 U.S.C. § 103.

Applicant respectfully traverses the Examiner's rejection for the following reasons. JP 2000336024A describes cosmetic compositions that comprise moisture-retaining plant extracts, which may include a plant extract from *Chenopodium quinoa*. As noted by the Examiner, JP 2000336024A fails to teach or even suggest that plant extracts from

*Chenopodium quinoa* are capable of inhibiting MMP-9 activity or of increasing collagen production. In fact, as clearly stated at page 2 of the translated version of JP 2000336024A, the problem to be solved by JP 2000336024A is to provide a cosmetic composition that has sustained moisture-retention effects over extended periods. In this regard, Applicant respectfully directs the Examiner to pages 24-25 of the translated version of JP 2000336024A, where the ability of the *Chenopodium quinoa* plant extract to retard moisture loss from the surface of the skin is described. Applicant asserts that, contrary to the Examiner's suggestion, JP 2000336024A demonstrates that the intrinsic mechanism/pathway for the moisturising effect of the described *Chenopodium quinoa* plant extract is in fact through its ability to act effectively as a "barrier" thereby retaining moisture in the epidermal, or surface, layer of the skin. In contrast, matrix metalloproteases, including MMP-9, exert their activity at the cellular level, in particular within the extracellular matrix (ECM), which is also the location of the skin structural component, collagen (see, for example, page 2, lines 1-11, of the instant application). Applicant asserts that, as such, the skilled worker would not consider either MMP-9 activity or collagen production to play a role in preventing moisture loss from the epidermal surface. Moreover, Applicant asserts it is well-known in the art that the ability of a compound or composition to moisturise the skin is not necessarily an indication that the compound/composition inhibits MMP-9 or induces collagen production. If it were otherwise it could be claimed that any moisturising agent has anti-MMP-9 and collagen inducing effects, which the skilled worker would appreciate is certainly not the case. As such, Applicant asserts that the fact that a plant extract is described as having a moisturising effect on the skin in no way renders obvious its ability to inhibit MMP-9 activity or to induce collagen production.

In the instant application, Applicant has recognised and demonstrated that *Chenopodium quinoa* plant extracts, amongst others, have unexpected additional properties, including the ability to inhibit MMP-9 activity and increase collagen production. While moisturising the skin may have an indirect effect on maturing skin through water retention, it is known in the art that skin ageing, including the formation of wrinkles, is the direct result of structural changes that are due in large part to an increase in the activity of

certain matrix metalloproteases (MMPs) including MMP-9, as well as a concomitant increase in the breakdown of various components of the ECM, including collagen (see, for example, page 2, lines 10-21, and page 3, lines 10-23, of the instant application). The Applicant's recognition of the ability of the *Chenopodium quinoa* plant extracts to inhibit MMP-9 activity and increase collagen production and thus directly affect skin ageing phenomena through these activities, allowed the Applicant to identify additional uses for the plant extracts in ameliorating or preventing conditions associated with MMP-mediated skin structural changes including, for example, wrinkle formation or appearance, loss of skin elasticity and the like. Applicant asserts that since JP 2000336024A fails to recognise the ability of the *Chenopodium quinoa* plant extracts to inhibit MMP-9 activity and increase collagen production, the skilled worker having regard to JP 2000336024A would not have contemplated using *Chenopodium quinoa* plant extracts for uses that rely on these effects.

Solely in order to expedite prosecution of the instant application, however, Applicant has amended independent claim 26, currently on file, to specify that the recited plant extracts are each derived by solvent extraction of plant material from a specified plant and that the plant material from Chenopodium quinoa comprises Chenopodium quinoa seeds. Support for this amendment can be found, for example, at pages 195-196 (Table 9) and at page 202 (Table 11), which describe *Chenopodium quinoa* extracts derived from the seeds of the plant and their ability to inhibit MMP-9 and to increase collagen production. Independent claims 47, 48 and 49, which refer to the dermatological formulation of claim 26 likewise incorporate this amendment. Claims 47, 48 and 49 have been further amended to specify that the improving the appearance of skin comprises decreasing the appearance of wrinkles (claim 47), that the attenuating skin ageing comprises attenuating the formation of wrinkles (claim 48) and that the dermatological condition comprises skin wrinkling (claim 49).

Applicant submits that JP 2000336024A does not describe *Chenopodium quinoa seed* extracts. JP 2000336024A describes at page 4, paragraph 0007 of the translated version that the preparation of the plant extracts "is performed with the leaf, stem, root, flower, seed or whole plant." The specific Examples included in JP 2000336024A,

however, fail to indicate which part or parts of the *Chenopodium quinoa* plant are used to prepare the described extracts. Applicant asserts that the numerous plant parts and possible combinations presented by JP 2000336024A, taken together with the lack of guidance therein as to which plant parts to utilise to prepare a *Chenopodium quinoa* extract, are simply an invitation for the worker skilled in the art to experiment in order to identify a *Chenopodium quinoa* extract that has the required moisture-retaining properties. Moreover, given that, as noted above, nothing in JP 2000336024A teaches or suggests that a *Chenopodium quinoa* extract could be capable of inhibiting MMP-9 activity and of increasing collagen production and thus of ameliorating the effects of structural changes in the skin, Applicant further asserts that this reference fails to anticipate or render obvious a dermatological composition comprising a *Chenopodium quinoa* seed extract and methods of using same to decrease the appearance of wrinkles, attenuate the formation of wrinkles or treat skin wrinkling, as recited in independent claims 26, 47, 48 and 49, submitted herewith. Accordingly, Applicant submits that claims 26, 30-33, 35 and 45-55, submitted herewith, comply with 35 U.S.C. 102 (b) and 103 (a) and respectfully requests that the Examiner withdraw this rejection.

**Conclusion**

Applicant believes that this Response has addressed all items in the Office Action and now places the application in condition for allowance. Accordingly, favorable reconsideration and allowance of claims 26 and 30 to 58 at an early date is solicited. Applicant petitions for a three-month extension of time to allow timely response up to and including May 13, 2008. The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 08-1641. Should any issues remain unresolved, the Examiner is invited to telephone the undersigned.

Respectfully submitted,  
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